



ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2012-0132; FRL-9384-3]

Glyphosate; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of glyphosate in or on multiple commodities which are identified and discussed later in this document.

Interregional Research Project Number 4 (IR-4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective [*insert date of publication in the Federal Register*].

Objections and requests for hearings must be received on or before [*insert date 60 days after date of publication in the Federal Register*], and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the

SUPPLEMENTARY INFORMATION).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2012-0132, is available at <http://www.regulations.gov> or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), EPA West Bldg., Rm. 3334, 1301 Constitution Ave., NW., Washington, DC 20460-0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPP Docket is (703) 305-5805. Please review the visitor

instructions and additional information about the docket available at

<http://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: Andrew Ertman, Registration Division, Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 308-9367; email address: ertman.andrew@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

B. How Can I Get Electronic Access to Other Related Information?

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR site at http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl.

C. How Can I File an Objection or Hearing Request?

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2012-0132 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before [*insert date 60 days after date of publication in the **Federal Register***]. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA-HQ-OPP-2012-0132, by one of the following methods:

- *Federal eRulemaking Portal*: <http://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

- *Mail*: OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

• *Hand Delivery*: To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <http://www.epa.gov/dockets/contacts.html>.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <http://www.epa.gov/dockets>.

II. Summary of Petitioned-For Tolerance

In the **Federal Register** of May 2, 2012 (77 FR 25954) (FRL-9346-1), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 2E7979) by IR-4, 500 College Rd. East, Suite 201 W, Princeton, NJ 08540. The petition requested that 40 CFR 180.364 be amended by establishing tolerances for residues of the herbicide glyphosate *N*-(phosphonomethyl) glycine in or on the raw agricultural commodity teff, forage and teff, hay at 100 parts per million (ppm) and oilseed crops, group 20 at 40 ppm. The petition also requested amendments to the tolerances in 40 CFR 180.364 as follows: Vegetable, root and tuber, group 1, except sugar beet, from 0.2 ppm to 6.0 ppm; vegetable, bulb, group 3 at 0.2 ppm to vegetable, bulb, group 3-07 at 0.2 ppm; okra at 0.5 ppm; vegetable, fruiting, group 8 at 0.1 ppm to vegetable, fruiting, group 8-10 at 0.1 ppm; fruit, citrus, group 10 at 0.5 ppm to fruit, citrus, group 10-10 at 0.5 ppm; fruit, pome, group 11 at 0.2 ppm to fruit, pome, group 11-10 at 0.2 ppm; cranberry, grape, juneberry, kiwifruit, lingonberry, salal, strawberry, and berry group 13 at 0.2 ppm to berry and small fruit, group 13-07 at 0.2 ppm. That document referenced a summary of the petition prepared by Monsanto, the registrant, which is available in the docket at

<http://www.regulations.gov>. There were no comments received in response to the notice of filing.

Based upon review of the data supporting the petition, EPA has modified the levels at which tolerances are being established for some commodities as well as the crops for which tolerances are being established. The reason for these changes is explained in Unit IV.C.

III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is “safe.” Section 408(b)(2)(A)(ii) of FFDCA defines “safe” to mean that “there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.” This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to “ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue....”

Consistent with FFDCA section 408(b)(2)(D), and the factors specified in FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for glyphosate including

exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with glyphosate follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

A chronic feeding/carcinogenicity study in rats found no systemic effects in any of the parameters examined (body weight, food consumption, clinical signs, mortality, clinical pathology, organ weights, and histopathology). A second chronic feeding/carcinogenicity study in rats tested at higher dietary levels, and a lowest-observed-adverse-effect level (LOAEL) was identified at 20,000 ppm (approximately 940 milligram/kilogram/day (mg/kg/day)) based on decreased body-weight gains in females and increased incidence of cataracts and lens abnormalities, decreased urinary pH, increased absolute liver weight, and increased relative liver weight/brain weight in males. No evidence of carcinogenicity was found in mice or rats. In a chronic toxicity study in dogs, no systemic effects were found in all examined parameters.

There is no quantitative or qualitative evidence of increased susceptibility of rat or rabbit fetuses to *in utero* exposure in developmental studies. A focal tubular dilation of the kidneys was observed in an older 3-generation reproductive study on rats at the 30-mg/kg/day level (highest dose tested (HDT)); however, a 2-generation reproductive study on rats did not observe the same effect at the 1,500 mg/kg/day level (HDT), nor were any

adverse reproductive effects observed at any dose level. A clear NOAEL was established and the chronic reference dose (cRfD) was set at a level well below this effect.

Neurotoxicity has not been observed in any of the acute, subchronic, chronic, developmental, or reproductive studies performed with glyphosate.

Neurotoxicity screening battery tests and an immunotoxicity study have been submitted to the Agency. Given the timing of the submission of these studies, the Agency has conducted preliminary reviews of these studies. The preliminary reviews show no effects up to the HDT for both the acute and subchronic durations for the neurotoxicity studies and no effects up to the HDT in the immunotoxicity study. EPA does not believe that further review will result in different conclusions concerning the neurotoxic or immunotoxic potential of glyphosate.

Specific information on the studies received and the nature of the adverse effects caused by glyphosate as well as the NOAEL and the LOAEL from the toxicity studies can be found at <http://www.regulations.gov> in the document entitled “Glyphosate. Section 3 Registration Concerning the Application of Glyphosate to Carrots, Sweet Potato, Teff, and Oilseeds (Crop Group (CG) 20) and to Update the CG Definitions for Bulb Vegetable (CG 3-07), Fruiting Vegetable (CG 8-10), Citrus Fruit (CG 10-10), Pome Fruit (CG 11-10), and Berry (CG 13-07). Human-Health Risk Assessment” on pp. 26-28 in docket ID number EPA-HQ-OPP-2012-0132.

B. Toxicological Points of Departure/Levels of Concern

Once a pesticide’s toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below

which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level -- generally referred to as a population-adjusted dose (PAD) or a RfD -- and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see <http://www.epa.gov/pesticides/factsheets/riskassess.htm>.

A summary of the toxicological endpoints for glyphosate used for human risk assessment is discussed in Unit III.B. of the final rule published in the **Federal Register** of April 8, 2011 (76 FR 19701) (FRL-8866-8).

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to glyphosate, EPA considered exposure under the petitioned-for tolerances as well as all existing glyphosate tolerances in 40 CFR 180.364. EPA assessed dietary exposures from glyphosate in food as follows:

i. *Acute exposure.* Quantitative acute dietary exposure and risk assessments are performed for a food-use pesticide, if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure.

No such effects were identified in the toxicological studies for glyphosate; therefore, a quantitative acute dietary exposure assessment is unnecessary.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used food consumption information from the United States Department of Agriculture (USDA) National Health and Nutrition Examination Survey, What We Eat in America, (NHANES/WWEIA). This dietary survey was conducted from 2003 to 2008. As to residue levels in food, EPA assumed tolerance level residues and 100 percent crop treated (PCT) for both proposed and existing commodities.

iii. *Cancer.* Based on the data summarized in Unit III.A., EPA has concluded that glyphosate does not pose a cancer risk to humans. Therefore, a dietary exposure assessment for the purpose of assessing cancer risk is unnecessary.

iv. *Anticipated residue and percent crop treated (PCT) information.* EPA did not use anticipated residue and/or PCT information in the dietary assessment for glyphosate. Tolerance level residues and/or 100 PCT were assumed for all food commodities.

2. *Dietary exposure from drinking water.* The Agency used both a screening level water exposure model (surface water) as well as monitoring data (ground water) in the dietary exposure analysis and risk assessment for glyphosate in drinking water. The simulation model takes into account data on the physical, chemical, and fate/transport characteristics of glyphosate. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at <http://www.epa.gov/oppefed1/models/water/index.htm>.

Based on the Pesticide Root Zone Model /Exposure Analysis Modeling System (PRZM/EXAMS) and monitoring data from the National Water-Quality Assessment

Program (NAWQA), the estimated drinking water concentrations (EDWCs) of glyphosate for chronic exposures are estimated to be 8.11 parts per billion (ppb) for surface water and 2.03 ppb for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For chronic dietary risk assessment, the water concentration of value 8.11 ppb was used to assess the contribution to drinking water.

3. *From non-dietary exposure.* The term “residential exposure” is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets).

Glyphosate is currently registered for the following uses that could result in residential exposures: Turf (including golf courses and residential lawns) and for aquatic application. EPA assessed residential exposure using the following assumptions:

Based on the registered residential use patterns, there is a potential for short-term dermal and inhalation exposures to homeowners who mix and apply products containing glyphosate (residential handlers). However, since short- and intermediate-term dermal or inhalation endpoints were not selected, a quantitative exposure risk assessment was not completed.

Based on the registered use patterns, children 1-2 years old may have short-term post-application incidental oral exposures from hand-to-mouth behavior on treated lawns and swimmers (adults and children 3-6 years old) may have short-term post-application incidental oral exposures from aquatic uses. Based on the soil half-life for glyphosate, intermediate-term soil ingestion was also considered for children 1<2 years old. The incidental oral scenarios for the turf assessment (i.e., hand-to-mouth, object-to-mouth,

and soil ingestion) should be considered inter-related and it is likely that they occur interspersed amongst each other across time. Combining these scenarios would be overly conservative because of the conservative nature of each individual assessment.

Therefore, none of the incidental oral scenarios were combined.

Further information regarding EPA standard assumptions and generic inputs for residential exposures may be found at

<http://www.epa.gov/pesticides/trac/science/trac6a05.pdf>.

4. *Cumulative effects from substances with a common mechanism of toxicity.*

Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider “available information” concerning the cumulative effects of a particular pesticide's residues and “other substances that have a common mechanism of toxicity.”

EPA has not found glyphosate to share a common mechanism of toxicity with any other substances, and glyphosate does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that glyphosate does not have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's website at *<http://www.epa.gov/pesticides/cumulative>*.

D. Safety Factor for Infants and Children

1. *In general.* Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database

on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the Food Quality Protection Act Safety Factor (FQPA SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional SF when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity.* There is no quantitative or qualitative evidence of increased susceptibility of rat or rabbit fetuses to *in utero* exposure in developmental studies. A focal tubular dilation of the kidneys was observed in an older 3-generation reproductive study on rats at the 30-mg/kg/day level (HDT); however, a 2-generation reproductive study on rats did not observe the same effect at the 1,500 mg/kg/day level (HDT), nor were any adverse reproductive effects observed at any dose level. A clear NOAEL was established and the cRfD was set at a level well below this effect. Therefore, the endpoints selected for risk assessment are protective of the effects seen in the 3-generation rat reproduction study.

3. *Conclusion.* EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF were reduced to 1X. That decision is based on the following findings:

- i. The toxicity database for glyphosate is complete.
- ii. There is no indication that glyphosate is a neurotoxic chemical and there is no need for a developmental neurotoxicity study or additional uncertainty factors (UFs) to account for neurotoxicity.
- iii. As discussed in Unit III.D.2., there is no evidence that glyphosate results in increased susceptibility in *in utero* rats or rabbits in the prenatal developmental studies.

iv. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessments were performed based on 100 PCT and tolerance-level residues. EPA made conservative (protective) assumptions in the surface water modeling used to assess exposure to glyphosate in drinking water. EPA used similarly conservative assumptions to assess post-application incidental oral exposure of children. These assessments will not underestimate the exposure and risks posed by glyphosate.

E. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute PAD (aPAD) and chronic PAD (cPAD). For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate MOE exists.

1. *Acute risk.* An acute aggregate risk assessment takes into account acute exposure estimates from dietary consumption of food and drinking water. No adverse effect resulting from a single oral exposure was identified and no acute dietary endpoint was selected. Therefore, glyphosate is not expected to pose an acute risk.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to glyphosate from food and water will utilize 13% of the cPAD for children 1-2 years old, the population group receiving the greatest exposure. Based on the explanation in Unit III.C.3., regarding residential use patterns, chronic residential exposure to residues of glyphosate is not expected.

3. *Short-term risk.* Short-term aggregate exposure takes into account short-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

Glyphosate is currently registered for uses that could result in short-term residential exposure, and the Agency has determined that it is appropriate to aggregate chronic exposure through food and water with short-term residential exposures to glyphosate.

Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded the combined short-term food, water, and residential exposures result in aggregate MOEs of 2,000 for the general U.S. population and 450 for children 1-2 years old. Because EPA's level of concern for glyphosate is a MOE of 100 or below, these MOEs are not of concern.

4. *Intermediate-term risk.* Intermediate-term aggregate exposure takes into account intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

Glyphosate is currently registered for uses that could result in intermediate-term residential exposure to children 1-2 years old, and the Agency has determined that it is appropriate to aggregate chronic exposure through food and water with intermediate-term residential exposures to glyphosate.

Using the exposure assumptions described in this unit for intermediate-term exposures, EPA has concluded that the combined intermediate-term food, water, and residential exposures result in an aggregate MOE of 770 for children 1-2 years old, the

population subgroup of concern. Because EPA's level of concern for glyphosate is a MOE of 100 or below, these MOEs are not of concern.

5. *Aggregate cancer risk for U.S. population.* Based on the lack of evidence of carcinogenicity in two adequate rodent carcinogenicity studies, glyphosate is not expected to pose a cancer risk to humans.

6. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population or to infants and children from aggregate exposure to glyphosate residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (high-performance liquid chromatography (HPLC)) is available to enforce the tolerance expression.

The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755-5350; telephone number: (410) 305-2905; email address: *residuemethods@epa.gov*.

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint United Nations Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade

agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

The Codex has established MRLs for glyphosate in or on cotton seed at 40 ppm, sunflower seed at 7 ppm, and rape seed at 20 ppm. The MRL for cotton seed is the same as the oilseed crop group tolerance and the MRL for rape seed is the same as the canola seed tolerance being established by this document. Based on the oilseed residue data, harmonization with the Codex sunflower seed tolerance is not possible.

C. Revisions to Petitioned-For Tolerances

The Agency has revised the petitioned-for tolerances as follows:

The proposed increase in tolerance for vegetables, root and tuber, group 1, except sugar beet from 0.2 ppm to 6 ppm cannot be done at this time due to inadequate residue data. Instead, the Agency is establishing individual tolerances for carrot at 5.0 ppm and sweet potato at 3.0 ppm and modifying the existing tolerance on vegetables, root and tuber, group 1, except sugar beet at 0.20 ppm to read as “vegetables, root and tuber, group 1, except sugar beet, carrot, and sweet potato.”

The petition requested a tolerance at 40 ppm on the oilseed group 20. In order to maintain harmonization with both Canada and Codex the Agency is establishing a tolerance on the oilseed crop group 20, except canola at 40 ppm and is maintaining the existing canola seed tolerance at 20 ppm.

The petition requested that the current tolerance for vegetable, fruiting, group 8 be updated to the new vegetable, fruiting, group 8-10. Okra is part of the new crop group, however, and the currently established tolerance in or on crop group 8 is 0.1 ppm,

whereas the okra tolerance is 0.5 ppm. Due to this difference, the Agency is updating crop group 8 to read “vegetable, fruiting, group 8-10, except okra” and maintaining the existing okra tolerance at 0.5 ppm.

Lastly, several of the tolerance values on the crop group conversions are being revised to reflect Agency policy concerning significant figures.

V. Conclusion

Therefore, tolerances are established for residues of glyphosate *N*-(phosphonomethyl) glycine in or on the raw agricultural commodity teff, forage at 100 ppm; teff, hay at 100 ppm; oilseeds, group 20, except canola at 40 ppm; vegetable, root and tuber, group 1, except carrot, sweet potato, and sugar beet at 0.20 ppm; carrot at 5.0 ppm; sweet potato at 3.0 ppm; vegetable, bulb, group 3-07 at 0.20 ppm; vegetable, fruiting, group 8-10 (except okra) at 0.10 ppm; fruit, citrus, group 10-10 at 0.50 ppm; fruit, pome, group 11-10 at 0.20 ppm; and berry and small fruit, group 13-07 at 0.20 ppm.

In addition, due to the establishment of the tolerances in this document, the following tolerances are being removed as unnecessary: Vegetables, root and tuber, crop group 1, except sugar beet; vegetable, bulb, group 3; vegetable, fruiting, group 8; fruit, citrus, group 10; fruit, pome, group 11; berry group 13; borage, seed; cotton, undelinted seed; crambe, seed; flax, meal; flax, seed; jojoba seed; lesquerella, seed; meadowfoam, seed; mustard seed; rapeseed, seed; safflower, seed; sesame, seed; sunflower, seed; cranberry; grape; juneberry; kiwifruit; lingonberry; salal; and strawberry.

VI. Statutory and Executive Order Reviews

This final rule establishes tolerances under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has

exempted these types of actions from review under Executive Order 12866, entitled “Regulatory Planning and Review” (58 FR 51735, October 4, 1993). Because this final rule has been exempted from review under Executive Order 12866, this final rule is not subject to Executive Order 13211, entitled “Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use” (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled “Protection of Children from Environmental Health Risks and Safety Risks” (62 FR 19885, April 23, 1997). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it require any special considerations under Executive Order 12898, entitled “Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations” (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), do not apply.

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined

that Executive Order 13132, entitled “Federalism” (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled “Consultation and Coordination with Indian Tribal Governments” (65 FR 67249, November 9, 2000) do not apply to this final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (2 U.S.C. 1501 *et seq.*).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA) (15 U.S.C. 272 note).

VII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a “major rule” as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: April 19, 2013.

Daniel J. Rosenblatt,

Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180--[AMENDED]

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

2. In § 180.364:

- a. Add alphabetically to the table in paragraph (a)(1) the following commodities.

- b. Remove from the table in paragraph (a)(1), the commodities berry group 13;

borage, seed; cotton, undelinted seed; crambe, seed; cranberry; flax, meal; flax, seed; fruit, citrus, group 10; fruit, pome, group 11; grape; jojoba seed; juneberry; kiwifruit; lesquerella, seed; lingonberry; meadowfoam, seed; mustard seed; rapeseed, seed; safflower, seed; salal; sesame, seed; strawberry; sunflower, seed; vegetable, bulb, group 3; vegetable, fruiting, group 8; vegetable, root and tuber, group 1, except sugar beet.

The additions read as follows:

§ 180.364 Glyphosate; tolerances for residues.

(a) General. (1) * * *

Commodity	Parts per million
* * *	* *
Berry and small fruit, group 13-07	0.20
* * *	* *
Carrot	5.0
* * *	* *
Fruit, citrus, group 10-10	0.50
Fruit, pome, group 11-10	0.20
* * *	* *
Oilseeds, group 20, except canola	40
* * *	* *
Sweet potato	3.0
* * *	* *
Teff, forage	100
* * *	* *
Teff, hay	100

*	*	*	*	*
Vegetable, bulb, group 3-07			0.20	
*	*	*	*	*
Vegetable, fruiting, group 8-10 (except okra)			0.10	
*	*	*	*	*
Vegetables, root and tuber, group 1, except carrot, sweet potato, and sugar beet			0.20	
*	*	*	*	*

* * * *

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